Remarks

Claims 1-12, 14-22 and 137 are pending. Claims 1 and 21 have been amended to remove the reference to "per se" and to incorporate the subject matter of claim 13. Said amendments are not an admission or acknowledgement in any fashion that the phrase "per se" is equivalent to the subject matter of claim 13. Claim 1 has also been amended to incorporate the requirement for cooling of the flowable material in the molding cavity, as described in part in claims 2, 3 and throughout the specification, to form a solid molded dosage form. No new matter has been added.

The Examiner rejects claims 1, 6-10 and 137 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,830,502 ("Dong et al."). The Examiner rejects claims 14-20, 22 and 137 under 35 U.S.C. 103 as being unpatentable over Dong in view of U.S. Patent No. 6,177,125 ("Voss et al."). Applicants submit that each of these rejections is rendered moot by the amendments made above.

The Examiner has objections and rejections premised on the use of "per se" in the claims. This element has been eliminated from the claims to overcome these objections and rejections.

The Examiner rejects claims 1-5, 11-13, 21 and 137 (now 1-5, 11, 12, 21 and 137) under 35 U.S.C. 103 as being unpatentable over Dong. Applicants respectfully traverse this rejection.

Claim 1 is directed to a method of making a dosage form containing a first medicant. The process requires the steps of injecting through a nozzle a flowable material containing said first medicant into a mold cavity and hardening said flowable material into a solid molded dosage form having a shape substantially the same as the mold cavity. The flowable material injected into the mold cavity must contain at least one medicant. Additionally, substantially all of the flowable material injected into the mold cavity becomes part of the solid molded dosage form. The dosage forms contemplated by Dong do not satisfy all of these requirements.

The Examiner argues that the compositions of Dong contain a medicament and that the claims are broad enough to read on the process shown in Dong. Dong describes a process for making an osmotic device having an injection molded housing member. The molding compositions contain "thermoplastic polymer, or copolymer, or the compositions comprise a mixture of thermoplastic polymers and optional injection-molding ingredients." Col. 3, lines

8-10. Subsequently, Dong teaches that the compositions can comprise 100% thermoplastic polymer or a blend of polymers, "with all polymers equal to 100%." Col. 3, line 44.

The therapeutic agent for Dong is taught as being incorporated in conventional manner. One embodiment presses the therapeutic agent into a solid shape that can be pressed into the internal dimensions of the dosage form. A second embodiment presses the therapeutic agent into a layer for incorporation into the dosage form. See passage in column 4, lines 39-55. The incorporation of a medicament in an outer molded shell would not be consistent with the primary purpose of an osmotic device, which is precise delivery of medicament through an opening using an osmagent and push composition. Hence, Dong fails to disclose at least one material feature of the claimed process - the presence of at least one medicament in the flowable material.

Claims 1 and 21 now provide that the substantially all of the flowable material injected into the mold cavity becomes part of the solid dosage form. Dong, at best, describes a process for making an injected molded chamber having a hollow portion that is subsequently filled with a therapeutic agent. The molded article in Dong is not a solid dosage form. Dong does not produce a solid dosage form containing a first medicament wherein substantially all of the flowable material injected into the mold cavity becomes part of the solid dosage form.

For all of the reasons above, Applicants request that the Examiner reconsider and withdraw her obviousness rejection of claims 1-5, 11, 12, 21 and 137 in view of Dong.

The Examiner rejects claims 1, 2, 6-10, 13 and 137 (now claims 1, 2, 6-10 and 137) under 102(e) as being anticipated by U.S. Patent No. 6,737,005 ("Rosenberg"). Applicants respectfully traverse this rejection.

Rosenberg describes a process for producing a solid dosage form by shaping a plastic mixture into a solid dosage form in a molding calendar with two counter-rotating molding rolls. Rosenberg contemplates that the calendar roll process will produce dosage forms in a "tablet ribbon" form "in which the individual dosage forms are still connected together by narrow flashes.." Col. 3, lines 1-3. Hence, Rosenberg does not disclose or suggest a process wherein substantially all of the flowable material injected into the mold cavity becomes part of the molded dosage form. Rosenberg also describes a separate cooling step following demolding.

See column 3, lines 7-8. Claim 1 now requires cooling of the molded dosage form in the mold cavity.

Claim 10 provides that the flowable material comprises gelatin. The specification notes that gelatin is an extremely different material to use as an injection molded material for making dosage forms. Gelatins, once hydrated, have a very abrupt transition temperature between the liquid and solid/gel phases. See publication of instant application, US 2003/0086973 A1, paragraph 173. None of the exemplified resins in Rosenberg or noted by the Examiner contemplate or are equivalent to a gelatin or gelatin-like material.
For all of the foregoing reasons, Applicants request that the Examiner reconsider and withdraw her anticipation rejection of claims 1, 2, 6-10 and 137 in view of Rosenberg.

Applicants submit that the present application is now in condition for allowance. Applicants request that the Examiner contact the undersigned representative if minor amendments will further prosecution towards issuance.

Respectfully submitted,

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